K121083

OCT 11 2012

Revised 510(k) Summary

Submitter:	Loma Vista Medical 863A Mitten Road, Suite 100A Burlingame, CA 94010 Phone: (650) 490-4747 Fax: (650) 240-0761 Email: paul@lomavistamedical.com
Contact Person:	Tiffini Diage 1307 South Mary Avenue, Suite 280 Sunnyvale, CA 94087 Phone: (707) 799-6732 Fax: (408) 462-9132 Email: tdiage@namsa.com
Date Prepared:	8/27/2012
Trade Name:	TRUE Dilatation™ Balloon Valvuloplasty Catheter
Classification:	Class II Balloon Aortic Valvuloplasty 21 CFR 870.1255
Product Code:	OZT
Predicate Device(s):	The subject device is equivalent to the following devices: NuCLEUS, 510(k) number K082776
Device Description:	The Loma Vista Medical (LVM) TRUE Dilatation™ Catheter is a coaxial catheter with a balloon fixed at the tip used for Balloon Aortic Valvuloplasty (BAV) of the aortic valve. The effective length of the catheter is 110 cm and it has two lumens: one lumen is used to inflate and deflate the balloon and the other permits the use of a guidewire to position the catheter. The balloon inflation luer-lock hub (angled) connects to a syringe inflation device to deliver radiopaque contrast media for inflation. The guidewire luer-lock hub (straight) connects to the guidewire lumen.
Indication for Use:	The TRUE Dilatation™ Catheter is indicated for balloon aortic valvuloplasty.
Functional and Safety Testing:	To verify that the device design met its functional and performance requirements, representative samples of the device underwent biocompatibility, sterility, packaging integrity, and mechanical testing in accordance with ISO 10993-1 2009, ISO 11135-1 2007, ASTM D4169:2009, ISO 10555-1 2009. Additional performance bench testing was performed and is summarized below.
In Vivo Performance Testing	Two separate European clinical studies were performed to confirm bench test data, to ensure design features continue to

	meet clinical needs, and to provide in vivo data to demonstrate safe and effective use of the TRUE Dilatation Catheter as to the predicate device. Data collected included device performance, procedural data, and clinical outcomes. Data was collected for 69 devices used in 69 clinical procedures. The data provides objective evidence that the TRUE Dilatation Catheter can be used safely and effectively in BAV procedures compared to the predicate device. In addition, the clinical experience confirms that the TRUE Dilatation Catheter can be successfully used for pre-dilatation prior to transcatheter aortic valve implantation, in comparison to the predicate. The success of the TAVI procedure confirms that the TRUE Dilatation Catheter as effective as the predicate in BAV procedures and allows for successful placement of TAVI devices. The absence of any adverse events (0/69) indicates that the device is safe as compared to the predicate. In addition, there have been no reports of any adverse events since the European commercial launch representing more than 400 TRUE procedures to date. The absence of device failures and device related adverse events demonstrates the equivalency of the TRUE Dilatation Catheter to the predicate NuCLEUS device.
Conclusion:	Loma Vista Medical considers the TRUE Dilatation Catheter to be substantially equivalent to the predicate device listed above. This conclusion is based upon the devices' similarities in principles of operation, performance requirements, and indications for use.

Test Performed	TRUE Dilatation Acceptance Criteria	TRUE Dilatation Results
Visual Inspection	When examined with 2.5X magnification, the external surface of the effective length of the catheter shall appear free from extraneous material, and process and surface defects.	61 of 61 catheters passed.
Balloon Preparation Test	Each catheter shall be prepped per the procedure without functional difficulties or anomalies.	61 of 61 catheters passed.
Diameter and Profile Test	Balloon diameter shall not deviate from stated balloon diameter by more than 1mm when inflated to 6 atm.	61 of 61 catheters passed.
Balloon Distensibility	Inflated balloon diameter shall not increase more than 2% between nominal inflation pressure (3 atm) and maximum inflation pressure (6 atm).	61 of 61 catheters passed.
Repeated Balloon Inflation	The balloon catheter shall not herniate or rupture after 10 inflation/deflation cycles to the maximum inflation pressure of 6 atm.	61 of 61 catheters passed.

Test Performed	TRUE Dilatation Acceptance Criteria	TRUE Dilatation Results
Balloon Minimum Burst Strength	The results must show statistically that with at least 95% confidence, 99.9% of the balloons will not burst at or below the maximum recommended rated burst pressure. All sizes must withstand a minimum of 6 atm.	A total of 98 samples across all device sizes tested and passed 95% confidence with 99.9% reliability.
Balloon Inflation / Deflation Test	The balloon shall inflate in no more than 5 seconds and deflate in no more than 10 seconds.	60 of 60 catheters met acceptance criteria.
Balloon Deflatability Test	There should be no interference with balloon deflation.	As evidenced by observed deflation, 60 0f 60 samples passed.
Tip Pull and Torque Test	Must withstand at least 10 turns without breaking.	20 of 20 catheters passed. No reported breaks. There is only 1 shaft size.
Bond Strength Test	All bonds must withstand at least 15N (3.4 lbs) pull strength.	29 of 29 samples passed.
Catheter Body Maximum Pressure Test	All samples must withstand 30 ATM (400 psi).	20 of 20 catheters withstood 30 ATM.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

OCT 11 2012

Loma Vista Medical
c/o Ms. Tiffini Diage
Regulatory Project Manager, NAMSA
1307 South Mary Avenue, Suite 280
Sunnyvale, CA 94807

Re: K121083
Trade Name: TRUE Dilatation™ Balloon Valvuloplasty Catheter
Regulation Number: 21 CFR 870.1255
Regulation Name: Balloon Aortic Valvuloplasty Catheter
Regulatory Class: Class II (two)
Product Code: OZT
Dated: August 24, 2012
Received: August 28, 2012

Dear Ms. Diage:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Indications for Use

510(k) Number (if known): K121083

Device Name: TRUE Dilatation Balloon Valvuloplasty Catheter

Indications For Use:

The TRUE Dilatation Balloon Valvuloplasty Catheter is indicated for balloon aortic valvuloplasty.

Prescription Use _X___ AND/OR Over-The-Counter Use ___
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)
(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices
510(k) Number K121083